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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,950	03/20/2002	Frederic J de Sauvage	P1748R1E	4737

7590 06/30/2004

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EXAMINER	
VIVLEMORE, TRACY ANN	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,950	DE SAUVAGE ET AL.	
	Examiner	Art Unit	
	Tracy Vivlemore	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-34 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-6, drawn to a method of treating a Th1-mediated disease in a mammal using a TCCR polypeptide antagonist wherein the antagonist is a small molecule.

Group II, claim(s) 1-5, 7-9, drawn to a method of treating a Th1-mediated disease in a mammal using a TCCR polypeptide antagonist wherein the antagonist is an antisense oligonucleotide.

Group III, claim(s) 1-5, 10, drawn to a method of treating a Th1-mediated disease in a mammal using a TCCR polypeptide antagonist wherein the antagonist is a TCCR variant lacking biological activity.

Group IV, claim(s) 1-5, 11-13, drawn to a method of treating a Th1-mediated disease in a mammal using a TCCR polypeptide antagonist wherein the antagonist is an antibody.

Group V, claim(s) 1-5, 14, drawn to a method of treating a Th1-mediated disease in a mammal using a TCCR polypeptide antagonist wherein the antagonist is a TCCR ligand.

Group VI, claim(s) 15-21, drawn to a method of treating a Th2-mediated disease in a mammal using a TCCR polypeptide or agonist wherein the agonist is a small molecule.

Group VII, claim(s) 15-20, 22, drawn to a method of treating a Th2-mediated disease in a mammal using a TCCR polypeptide or agonist wherein the agonist is a TCCR variant having biological activity.

Group VIII, claim(s) 15-20, 23-25, drawn to a method of treating a Th2-mediated disease in a mammal using a TCCR polypeptide or agonist wherein the agonist is an antibody.

Group IX, claim(s) 15-20, 26, drawn to a method of treating a Th2-mediated disease in a mammal using a TCCR polypeptide or agonist wherein the agonist is a stable TCCR ECD.

Group X, claim(s) 27, drawn to a method for determining the presence of a TCCR polypeptide in a cell using an anti-TCCR antibody.

Group XI, claim(s) 28, drawn to a method of diagnosing a Th1-mediated or Th2-mediated disease by detecting the level of expression of a gene encoding a TCCR polypeptide.

Group XII, claim(s) 29-31, drawn to a method of identifying a compound capable of inhibiting expression of a TCCR polypeptide.

Group XIII, claim(s) 32-34, drawn to a method of identifying a compound capable of inhibiting a biological activity of a TCCR polypeptide.

2. The inventions listed as groups I-XIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or

corresponding special technical features for the following reasons: groups I-V are drawn to methods of stimulating, enhancing or potentiating the differentiation of T-cells into the Th2 subtype. Groups VI-IX are drawn to methods of preventing the differentiation of T-cells into the Th2 subtype. The functions of these two groups of inventions are fundamentally opposite and thus cannot share a special technical feature.

3. The inventions of each of groups I-V lack a special technical feature because each group uses a different antagonist to treat Th1-mediated disease. In group I, the antagonist is a small molecule, in group II the antagonist is an antisense oligonucleotide, in group III the antagonist is a TCCR variant lacking biological activity, in group IV the antagonist is an antibody and in group V the antagonist is a TCCR ligand.

4. The inventions of each of groups VI-IX lack a special technical feature because each group uses a different agonist to treat Th2-mediated disease. In group VI, the agonist is a small molecule, in group VII the agonist is a TCCR variant having biological activity, in group VIII the agonist is an antibody and in group IX the antagonist is a stable TCCR ECD.

5. The inventions listed as groups I-V and the invention listed as group X lack a special technical feature for the following reasons: groups I-V are drawn to methods of stimulating, enhancing or potentiating the differentiation of T-cells into the Th2 subtype while group X is drawn to a method for determining the presence of a TCCR polypeptide in a cell using an anti-TCCR antibody.

6. The inventions listed as groups I-V and the invention listed as group XI lack a special technical feature for the following reasons: groups I-V are drawn to methods of stimulating, enhancing or potentiating the differentiation of T-cells into the Th2 subtype Group XI is drawn to a method of diagnosing a Th1-mediated or Th2-mediated disease by detecting the level of expression of a gene encoding a TCCR polypeptide.

7. The inventions listed as groups I-V and the invention listed as group XII lack a special technical feature for the following reasons: groups I-V are drawn to methods of stimulating, enhancing or potentiating the differentiation of T-cells into the Th2 subtype while group XII is drawn to a method of identifying a compound capable of inhibiting expression of a TCCR polypeptide.

8. The inventions listed as groups I-V and the invention listed as group XIII lack a special technical feature for the following reasons: groups I-V are drawn to methods of stimulating, enhancing or potentiating the differentiation of T-cells into the Th2 subtype while group XIII is drawn to a method of identifying a compound capable of inhibiting a biological activity of a TCCR polypeptide.

9. The inventions listed as groups VI-IX and group X lack a special technical feature for the following reasons: Groups VI-IX are drawn to methods of preventing the differentiation of T-cells into the Th2 subtype while group X is drawn to a method for determining the presence of a TCCR polypeptide in a cell using an anti-TCCR antibody.

10. The inventions listed as groups VI-IX and group XI lack a special technical feature for the following reasons: Groups VI-IX are drawn to methods of preventing the differentiation of T-cells into the Th2 subtype while group XI is drawn to a method of

diagnosing a Th1-mediated or Th2-mediated disease by detecting the level of expression of a gene encoding a TCCR polypeptide.

11. The inventions listed as groups VI-IX and group XII lack a special technical feature for the following reasons: Groups VI-IX are drawn to methods of preventing the differentiation of T-cells into the Th2 subtype while group XII is drawn to a method of identifying a compound capable of inhibiting expression of a TCCR polypeptide.

12. The inventions listed as groups VI-IX and group XIII lack a special technical feature for the following reasons: Groups VI-IX are drawn to methods of preventing the differentiation of T-cells into the Th2 subtype while group XIII is drawn to a method of identifying a compound capable of inhibiting a biological activity of a TCCR polypeptide.

13. The inventions listed as group X and group XI lack a special technical feature for the following reasons: group X is drawn to a method for determining the presence of a TCCR polypeptide in a cell using an anti-TCCR antibody while group XI is drawn to a method of diagnosing a Th1-mediated or Th2-mediated disease by detecting the level of expression of a gene encoding a TCCR polypeptide.

14. The inventions listed as groups X and group XII lack a special technical feature for the following reasons: group X is drawn to a method for determining the presence of a TCCR polypeptide in a cell using an anti-TCCR antibody while group XII is drawn to a method of identifying a compound capable of inhibiting expression of a TCCR polypeptide.

15. The inventions listed as groups X and group XIII lack a special technical feature for the following reasons: group X is drawn to a method for determining the presence of

a TCCR polypeptide in a cell using an anti-TCCR antibody while group XIII is drawn to a method of identifying a compound capable of inhibiting a biological activity of a TCCR polypeptide.

16. The inventions listed as groups XI and group XII lack a special technical feature for the following reasons: Group XI, claim(s) 28, drawn to a method of diagnosing a Th1-mediated or Th2-mediated disease by detecting the level of expression of a gene encoding a TCCR polypeptide while group XII is drawn to a method of identifying a compound capable of inhibiting expression of a TCCR polypeptide.

17. The inventions listed as groups XI and group XIII lack a special technical feature for the following reasons: Group XI, claim(s) 28, drawn to a method of diagnosing a Th1-mediated or Th2-mediated disease by detecting the level of expression of a gene encoding a TCCR polypeptide while group XIII is drawn to a method of identifying a compound capable of inhibiting a biological activity of a TCCR polypeptide.

18. The inventions listed as groups XII and group XIII lack a special technical feature for the following reasons: Group XII is drawn to a method of identifying a compound capable of inhibiting expression of a TCCR polypeptide while group XIII is drawn to a method of identifying a compound capable of inhibiting a biological activity of a TCCR polypeptide.

Species election

19. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

From claim 5: Allergic encephalomyelitis, multiple sclerosis, insulin-dependent diabetes mellitus, autoimmune uveoretinitis, inflammatory bowel disease and autoimmune thyroid disease. From claim 19: *Leishmania major, Mycobacterium leprae, Candida albicans, Toxoplasma gondi*, respiratory syncytial virus and human immunodeficiency virus. From claim 20: asthma, allergic rhinitis, atopic dermatitis and vernal conjunctivitis.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

20. The claims are deemed to correspond to the species listed above in the following manner. The following claim(s) are generic: claim 1 is generic to groups I-V, claim 15 is generic to groups VI-IX.

21. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or

corresponding special technical features for the following reasons: The species recited in claim 5 are distinct because each is a different disease with different causative agents, different symptoms and different methods of treatment. If any one of groups I-V is elected, applicant must further elect one of the following from claim 5: Allergic encephalomyelitis, multiple sclerosis, insulin-dependent diabetes mellitus, autoimmune uveoretinitis, inflammatory bowel disease and autoimmune thyroid disease.

22. The types of diseases recited in claim 18 are distinct because each is a distinct category of disease with different causative agents, different symptoms and different methods of treatment.

The species recited in claim 19 are distinct because each is a different infectious agent causing distinct diseases with unique symptoms and methods of treatment.

The species recited in claim 20 are distinct because each is a different allergic disorder affecting different systems of the body with distinct symptoms and treatments. If any of groups VI-IX is elected, applicant must further elect one of the following: infectious diseases or allergic disorders and then further elect one of the species in claim 19 or claim 20.

23. A telephone call was made to Denise Kettelberger on June 8, 2004 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

24. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:45-5:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Leguyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Lacourciere
KAREN A. LACOURCIERE, PH.D
PRIMARY EXAMINER

Tracy Vivlemore
Examiner
Art Unit 1635

TV
May 27, 2004